



## **HETLIOZ® is Now Available for the Treatment of Non-24-Hour Sleep-Wake Disorder in Germany**

August 1, 2016

**- HETLIOZ® (tasimelteon) is the first and only product to receive approval for the treatment of Non-24 in the European Union**

WASHINGTON, Aug. 1, 2016 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced that HETLIOZ® (tasimelteon) is now available for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in Germany.

"The launch of HETLIOZ in Germany reflects our continued focus to bring a treatment option to Non-24 patients across the globe," said Gian Piero Reverberi, Vanda's Senior Vice President and Chief Commercial Officer. "We are very pleased with our first HETLIOZ launch outside of the United States and look forward to making HETLIOZ available in additional countries in the coming years."

In July 2015, the European Commission (EC) approved HETLIOZ® for the treatment of Non-24 in totally blind adults in all 28 European Union (EU) member states as well as European Economic Area members Iceland, Liechtenstein and Norway.

### **About Non-24-Hour Sleep-Wake Disorder**

Non-24 is a chronic, circadian rhythm disorder resulting from the misalignment of the endogenous master body clock to the 24-hour day, disrupting the sleep-wake cycle. The sleep disturbance causes significant distress or impairment in social, occupational and other important areas of functioning.

### **About HETLIOZ®**

HETLIOZ® is a melatonin receptor agonist. HETLIOZ® has been approved by the EC and received orphan drug designation for the treatment of Non-24 in totally blind adults in the EU. For full EU prescribing information, please visit <http://www.ema.europa.eu>.

HETLIOZ® has been approved by the U.S. Food and Drug Administration and received orphan drug designation for the treatment of Non-24. For full U.S. prescribing information, please visit [www.hetlioz.com](http://www.hetlioz.com).

### **U.S. Indication and Important Safety Information About HETLIOZ®**

#### **Indication**

In the U.S., HETLIOZ® is indicated for the treatment of Non-24.

#### **Important Safety Information**

HETLIOZ® may cause somnolence: After taking HETLIOZ®, patients should limit their activity to preparing for going to bed, because HETLIOZ® can impair the performance of activities requiring complete mental alertness.

The most common adverse reactions (incidence >5% and at least twice as high on HETLIOZ® than on placebo) were headache, increased alanine aminotransferase, nightmares or unusual dreams, upper respiratory or urinary tract infection. The risk of adverse reactions may be greater in elderly (>65 years) patients than younger patients because exposure to HETLIOZ® is increased by approximately 2-fold compared with younger patients.

Use of HETLIOZ® should be avoided in combination with fluvoxamine or other strong CYP1A2 inhibitors, because of a potentially large increase in exposure of HETLIOZ®, and a greater risk of adverse reactions. HETLIOZ® should be avoided in combination with rifampin or other CYP3A4 inducers, because of a potentially large decrease in exposure of HETLIOZ®, with reduced efficacy.

There are no adequate and well-controlled studies of HETLIOZ® in pregnant women. Based on animal data, HETLIOZ® may cause fetal harm. HETLIOZ® should be used during pregnancy only if the potential benefit justifies the potential risks. Caution should be exercised when HETLIOZ® is administered to a nursing woman.

HETLIOZ® has not been studied in patients with severe hepatic impairment and is not recommended in these patients.

Safety and effectiveness of HETLIOZ® in pediatric patients have not been established.

### **About Vanda Pharmaceuticals Inc.**

Vanda is a specialty pharmaceutical company focused on the development and commercialization of novel therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals, please visit [www.vandapharma.com](http://www.vandapharma.com).

### **CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS**

Various statements in this release are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, Vanda's ability to successfully commercialize (alone or with others) HETLIOZ® in additional countries and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2015 and quarterly report on Form 10-Q for the quarter ended June 30, 2016, which are on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda

makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

*HETLIOZ® is a registered trademark of Vanda Pharmaceuticals Inc.*

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